**09-J5000-24**

**Original Effective Date:09/15/25**

**Reviewed: 08/13/25**

**Revised: 01/01/26**

# Subject: Telisotuzumab Vedotin (Emrelis) IV infusion

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|---|---|---|---|---|
| Dosage/ Administration | Position Statement | Billing/Coding | Reimbursement | Program Exceptions |
| Definitions | Related Guidelines | Other | References | Updates |


## DESCRIPTION:

Telisotuzumab vedotin (Emrelis), a c-Met-directed antibody-drug conjugate, was approved by the U.S. Food and Drug Administration (FDA) in May 2025 for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (OE) who have received a prior systemic therapy. High c-Met protein OE is defined as ≥50% of tumor cells with strong (3+) staining as determined by an FDA-approved test.. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

The safety and efficacy of telisotuzumab was evaluated in a phase 2, open-label study (LUMINOSITY, NCT03539536) of patients with locally advanced or metastatic non-squamous, EGFR wild-type NSCLC with high c-Met protein overexpression who had received prior systemic therapy (n=84). Included patients (median age, 64 years) received telisotuzumab 1.9 mg/kg IV every two weeks until disease progression or unacceptable toxicity.

Telisotuzumab vedotin-tllv treatment resulted in an overall response rate (ORR) of 35% (95% CI, 24% to 46%; all partial responses) and a median duration of response of 7.2 months (n=29; 95% CI, 4.2 to 12 months). Duration of response was 6 months or greater in 59% of patients, and 12 months or greater in 21% of patients. The most common adverse reactions (occurring in 20% of patients or more) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

National Comprehensive Cancer Network (NCCN) Guidelines for Non-Small Cell Lung Cancer (Version 7.2025) contain recommendations for the use of telisotuzumab in NSCLC.

## POSITION STATEMENT:

Initiation of telisotuzumab vedotin (Emrelis) **meets the definition of medical necessity** for any of the following indications when all associated criteria are met:

1. Non-Small Cell Lung Cancer (NSCLC)
    a. Member is diagnosed with recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC)
    b. Telisotuzumab is used as subsequent systemic therapy as a single agent
    c. Member's disease has non-squamous (adenocarcinoma, large cell, NSCLC not otherwise specified) cell histology – laboratory documentation must be submitted
    d. Member's tumor is confirmed as EGFR wild-type with high c-Met protein overexpression defined as: c-Met/MET greater than or equal to 50% of tumor cells with strong (IHC 3+) staining – laboratory documentation of biomarker and mutation testing must be submitted
    e. Dose does not exceed 1.9 mg/kg every 2 weeks
2. Member has another FDA-approved or NCCN-supported diagnosis, and **BOTH** of the following criteria are met:
    a. **EITHER** of the following:
        i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
        ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation
    b. Dosage does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

**Approval duration**: 6 months

Continuation of telisotuzumab vedotin (Emrelis) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for treatment of NSCLC, or other FDA-approved or NCCN supported diagnosis, **OR** the member has previously met all indication-specific criteria.
2. Member's disease has not progressed on treatment with telisotuzumab
3. Dose does not exceed 1.9 mg/kg every 2 weeks

**Approval duration**: 1 year

## DOSAGE/ADMINISTRATION:

**FDA-approved**

- 1.9 mg/kg administered intravenously every 2 weeks until disease progression or unacceptable toxicity

**Dose Adjustments**

- See product label for dose reductions due to adverse reactions

**Drug Availability**

- For injection: 20 mg or 100 mg of telisotuzumab vedotin-tllv as a lyophilized powder in a single-dose vial

## PRECAUTIONS:

**Boxed Warning**

- None

**Contraindications**

- None

**Precautions/Warnings**

- Peripheral Neuropathy: Monitor patients for new or worsening peripheral neuropathy. Withhold, reduce the dose, or permanently discontinue EMRELIS based on the severity
- Interstitial Lung Disease (ILD)/Pneumonitis: Severe, life-threatening or fatal ILD/pneumonitis may occur. Withhold or permanently discontinue EMRELIS based on the severity
- Ocular Surface Disorders: Monitor patients for signs or symptoms of ocular surface disorders, including vision changes. Withhold or permanently discontinue EMRELIS based on the severity
- Infusion-Related Reactions (IRR): Monitor patients for IRR. Withhold, reduce the rate of infusion, or permanently discontinue EMRELIS based on the severity. For patients who experience IRR, administer premedications prior to subsequent infusions
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients about the potential risk to a fetus and to use effective contraception

## BILLING/CODING INFORMATION:

### HCPCS Coding

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|---|---|
| J9326 | Injection, telisotuzumab vedotin-tllv, 1 mg |

### ICD-10 Diagnosis Codes That Support Medical Necessity

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|---|---|
| C33 | Malignant neoplasm of trachea |
| C34.00 – C34.92 | Malignant neoplasm of bronchus or lung |

## REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Part D:** Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

**Medicare Advantage:** No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

## DEFINITIONS:

None

## RELATED GUIDELINES:

None

## OTHER:

None

## REFERENCES:


1. Abbvie. Emrelis (telisotuzumab vedotin) injection, powder, lyophilized, for solution. 2025. [cited 8/1/25]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bc04f980-3957-4e35-ab81-8ec2ffe87215
2. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2025 [cited 8/1/25]. Available from: http://www.clinicalpharmacology.com/.
3. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 8/1/25]. Available from: http://clinicaltrials.gov/.
4. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 8/1/25].
5. NCCN Drugs & Biologics Compendium [Internet]. Fort Washington (PA): National Comprehensive Cancer Network; 2019 [cited 7/27/17]. Available from: http://www.nccn.org/professionals/drug_compendium/content/contents.asp/.

6. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2025 [cited 8/1/25]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.

## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 8/13/25.

## GUIDELINE UPDATE INFORMATION:

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| 09/15/25 | New Medical Coverage Guideline. |
| 10/01/25 | Revision: Added HCPCS code C9306. |
| 01/01/26 | Revision: Added HCPCS code J9326 and removed codes C9306 and J9999. |